IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CHARLES A. HARTJEN, M.D. **One Texas Station Court, Suite 300** **Lutherville, Maryland 21093,** **Plaintiff,**	:	
v.	:	**Case No.: MJG06CV2938**
CROSS MEDICAL PRODUCTS, INC. **181 Technology Drive** **Irvine, California 92618** **Serve: Corporate Creations Network, Inc.** **1308 Delaware Avenue** **Wilmington, Delaware 19806,** **Defendant.**	:	

FIRST AMENDED COMPLAINT

Plaintiff Charles A. Hartjen, M.D. ("plaintiff" or "Dr. Hartjen"), for his Complaint against defendant Cross Medical Products, Inc. ("defendant" or "Cross Medical"), hereby alleges as follows:

SUBJECT MATTER JURISDICTION AND VENUE

1. This is an action under the Patent Act of the United States, 35 U.S.C. § 256, seeking a declaration that plaintiff is a co-inventor of a patent that has been assigned to Cross Medical, and further claiming that Cross Medical has been unjustly enriched by failing and refusing to recognize plaintiff as a co-inventor of the patent.

2. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 in that it is an action between citizens of different states and the matter in controversy, exclusive of interest and costs, exceeds the sum or value of $75,000. This Court also has subject

matter jurisdiction over the matters complained pursuant to 35 U.S.C. § 256 and 28 USC. §§ 1331, 1338 and 2201.

3. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) in that Cross Medical resides in this district by virtue of the fact that its contacts in this district are sufficient to subject it to personal jurisdiction in this district.

THE PARTIES

4. Plaintiff is a Maryland resident and an orthopaedic surgeon having his principal place of business at One Texas Station Court, Suite 300, Lutherville, Maryland 21093.

5. On information and belief, Cross Medical is a Delaware corporation having its principal place of business at 191 Technology Drive, Irvine, California 92618.

UNDERLYING FACTS

6. On information and belief, Cross Medical is part of an independent public medical device company that offers orthopedic surgical implants used to stabilize and align the bones of a patient's spine.

7. On November 1, 1994, United States Patent No. 5,360,431 (the "'431 Patent"), entitled "Transpedicular Screw System and Method of Use" was issued to Ronald M. Puno ("Puno"), and Philip Mellinger ("Mellinger"). Puno and Mellinger thereafter assigned their rights in the '431 Patent to Cross Medical.

8. On December 12, 1995, United States Patent No. 5,474,555 (the "'555 Patent"), entitled "Spinal Implant System" was issued to Puno and Mellinger. Puno and Mellinger thereafter assigned their rights in the '555 Patent to Cross Medical.

9. In early 1988, defendant enlisted the assistance of Dr. Hartjen to serve as a clinical investigator exploring the use and efficacy of a spinal pedicle screw that was a

predecessor to the '431 and '555 Patent devices. This pedical screw was identified at the time as the "PWB I".

10. As part of that clinical investigation, Dr. Hartjen was requested to perform operations inserting the PWB I pedicle screw system in patients, and then to report the results of the implantation and performance of the PWB I system.

11. In mid-1988, Dr. Hartjen traveled to Louisville, Kentucky to perform practice insertions of the PWB I device on cadavers in preparation for its use on patients in the clinical study.

12. Thereafter, Dr. Hartjen returned to Baltimore, where he began his clinical investigation using the PWB I device on patients at the Greater Baltimore Medical Center.

13. On information and belief, Dr. Hartjen was one of the first, if not the first clinical investigator to insert the PWB I device in patients as part of the clinical study.

14. In January 1989, Dr. Hartjen performed his first such operation utilizing the PWB I device.

15. During the course of that operation, Dr. Hartjen experienced difficulty in the implantation and securitization of the PWB I system.

16. Specifically, the PWB I system required the surgeon, after inserting the screw into the patient's spine, to insert a rod into adjoining pedicle screws, and to tighten that rod into the pedicle screw by tightening a nut upwards from the patient's spine onto a cap and towards the top of the screw.

17. Dr. Hartjen found that the bottom-tightening feature of the PWB I device was rendered difficult to employ, both because of the awkward position of the nut vis-à-vis the surgeon, and because of the presence of blood, bone graft and soft tissue in the area.

18. Based on his experience in his first surgical procedure utilizing the PWB I system, Dr. Hartjen reported to the named inventors of the '431 and '555 Patents both the existence of this difficulty, and a suggestion for solving this problem.

19. Specifically, Dr. Hartjen suggested that the problem to be solved with the PWB I device was the difficulty encountered in tightening the nut in live patients because of the nut's position and the presence of blood and tissue.

20. Further, Dr. Hartjen suggested to the named inventors of the '431 and '555 Patents a solution to the problem: he suggested that the nut and the collar onto which it locked be relocated from beneath the spine rod to a position above the rod to make it easier to assemble and tighten.

21. Not surprisingly, the named inventors of the '431 and '555 Patents thereafter adopted Dr. Hartjen's suggestion, and modified the PWB I device to employ the "top loading" feature suggested by Dr. Hartjen.

22. This modified device came to be identified by defendant as the "PWB II" device, variations of which are the subject of both the '431 and '555 Patents.

23. Evidencing the import and efficacy of Dr. Hartjen's suggestion, one of the identified inventors of the '431 and '555 Patents co-authored a paper on the development of the '555 device entitled: "The Puno-Winter-Byrd (PWB) Spinal System for Transpedicular Fixation of the Lumbar Spine."

24. In that paper, the authors discussed the problem identified by Dr. Hartjen, and the employment of his proposed solution by stating as follows:

> There were several things learned during the pilot phase of this study. The surgeons found that implantation of the first version (Fig. 17.3: PWB I) was somewhat tedious because of the implant design. It was technically difficult to position the wrench when the nut was tightened, since it required that the nut be advanced from under the rod.

> Although it provided satisfactory fixation of the rod, the design was not "user friendly". A design improvement was in order and led to the development of the PWB II (Fig. 17.1), where the nut is applied from the top of the rod.

See Exhibit 1 to Complaint at p. 293 (emphasis supplied).

25. Defendant's internal documents likewise confirm the genesis of the change from the PWB I system to the PWB II system, as well as its timing.

26. For example, in a May 15, 1990 memorandum by The Buckman Company (which managed the investigational protocol on defendant's behalf) to surgeons participating in the study, Buckman wrote that "Based on the input from the operating surgeons for these 40 patients, the device has been modified to reduce the technical difficulty in implanting the system. The modification involved relocating the locking collar from beneath the spine rod to a position above the rod to facilitate intraoperative assembly." Exhibit 2 to Complaint (emphasis supplied).

27. Notwithstanding the fact that plaintiff made significant contributions to the conception of the devices covered by the '431 Patent and the '555 Patent, he was omitted as a co-inventor of these patents.

28. On information and belief, since the issuance of the '431 Patent and the '555 Patent, Cross Medical has derived and continues to derive a substantial amount of income therefrom.

29. Cross Medical has a significant economic stake in the validity of the patents involved here and hence in the correct inventorship designations on the patents.

30. Had plaintiff been properly named as a co-inventor, he would have been entitled to his share of the income flowing to Cross Medical from the patents.

COUNT I
(Correction of Inventorship Under 35 U.S.C. § 256)

31. Plaintiff incorporates by reference the allegations contained within paragraphs 1 through 30 of this Complaint as if fully set forth herein.

32. By virtue of his significant contributions to the conception of the devices covered by the '431 Patent and the '555 Patent, plaintiff should have been named as a co-inventor of these patents pursuant to 35 U.S.C. § 113.

33. Plaintiff's omission as a co-inventor of the '431 and '555 Patents was not the result of any deceptive intent on plaintiff's part.

34. Pursuant to 35 U.S.C. § 256, this Court may order correction of the patent on notice and hearing of all parties concerned.

WHEREFORE, plaintiff prays for a declaration that he is a co-inventor of the '431 Patent and the '555 Patent, and that the Court direct the Director of the United States Patent and Trademark Office to issue a certificate accordingly.

COUNT II
(Unjust Enrichment)

35. Plaintiff incorporates by reference the allegations contained within paragraphs 1 through 34 of this Complaint as if fully set forth herein.

36. On information and belief, since the issuance of the '431 Patent and the '555 Patent, Cross Medical has derived and continues to derive a substantial amount of income therefrom.

37. Had plaintiff been properly named as a co-inventor, he would have been entitled to his share of the income flowing to Cross Medical.

38. Under these circumstances, Cross Medical's acceptance and retention of all income generated from the '431 Patent and the '555 Patent make it inequitable for Cross Medical to retain the monies improperly withheld.

WHEREFORE, plaintiff demands judgment against Cross Medical in an amount to be proven at trial, plus pre-judgment and post-judgment interest, and such other and further relief as this Court deems appropriate.

Respectfully submitted,

TOBIN, O'CONNOR, EWING & RICHARD

By: /s/David C. Tobin

David C. Tobin, Esq. (Bar No. 03727)
Ziad P. Haddad, Esq. (Bar No. 14638)
5335 Wisconsin Avenue, N.W., Suite 700
Washington, D.C. 20015
Tel: (202) 362-5900
Fax: (202) 362-6579
Counsel for Charles A. Hartjen, M.D.

JURY DEMAND

A trial by jury is hereby demanded on all issues triable to a jury.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 15th day of December, 2006, a true and correct copy of the First Amended Complaint was sent by first-class, postage pre-paid U.S. mail to:

Mark A. Finkelstein, Esq.
Latham & Watkins LLP
650 Town Center Drive, 20th Floor
Costa Mesa, California 92626-1925

Nathaniel Vitan, Esq.
Latham & Watkins LLP
555 – 11th Street, N.W., Suite 1000
Washington, D.C. 20004-1304

/s/David C. Tobin
David C. Tobin